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**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

**TARO PHARMACEUTICALS NORTH  
AMERICA, INC., and  
TARO PHARMACEUTICALS U.S.A.,  
INC.,**

**Plaintiffs,**

**v.**

**SYNERX PHARMA, LLC,  
and DPT LABORATORIES, LTD.,**

**Defendants.**

**Civil Action No.  
09-03569-JLL-CCC**

**DOCUMENT FILED  
ELECTRONICALLY**

**Return Date: January 3, 2011**

**NOTICE OF MOTION FOR LEAVE TO FILE SECOND AMENDED  
ANSWER AND COUNTERCLAIMS OF SYNERX PHARMA, LLC  
AND  
SECOND AMENDED ANSWER OF DPT LABORATORIES, LTD.**

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*Taro Pharmaceuticals North America, Inc.*  
*Taro Pharmaceuticals U.S.A., Inc.*

**PLEASE TAKE NOTICE** that, pursuant to this Court's May 17, 2010 Amended Scheduling Order, on January 3, 2011 or as soon thereafter as counsel may be heard, the undersigned attorneys for Synerx Pharma, LLC and DPT Laboratories, Ltd. shall move before the Honorable Claire Cecchi, U.S.M.J., at the United States Post Office & Courthouse Building, 50 Walnut Street, Room MLK 2B, Newark, NJ 07101, for leave to file the Second Amended Answer and Counterclaims of Synerx Pharma, LLC and Second Amended Answer of DPT Laboratories, Ltd., in the form attached hereto as Exhibit "A," which contain additional bases and examples of invalidity of U.S. Patent No. 7,560,445.

**PLEASE TAKE FURTHER NOTICE** that Defendants rely upon the accompanying Brief of Defendants in Support of Motion for Leave to File the Second Amended Answer and Counterclaims of Synerx Pharma, LLC and Second Amended Answer of DPT Laboratories, Ltd., together with all papers currently on file with the Court and all papers and arguments Defendants may submit hereafter.

A Proposed Order is submitted herewith.

Respectfully submitted,

December 10, 2010

By: /s/ Karen A. Confoy

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a true copy of Defendants' Notice for Leave to File the Second Amended Answer and Counterclaims of Synerx Pharma, LLC and Second Amended Answer of DPT Laboratories, Ltd., supporting Brief, and proposed Order were electronically filed with the Clerk of Court using CM/ECF on December 10, 2010, which will send notification to the registered attorneys of record that the document has been filed and is available for viewing and downloading.

By: /s/ Karen A. Confoy  
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# **Exhibit A**

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**UNITED STATES DISTRICT COURT  
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**TARO PHARMACEUTICALS NORTH  
AMERICA, INC., and  
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**Plaintiffs and Counter-Defendants,**

**v.**

**SYNERX PHARMA, LLC,  
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**Civil Action No.  
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**SECOND AMENDED ANSWER AND  
COUNTERCLAIMS OF SYNERX PHARMA, LLC  
AND  
SECOND AMENDED ANSWER OF DPT LABORATORIES, LTD.**

Defendants Synerx Pharma, LLC ("Synerx") and DPT Laboratories, LTD ("DPT")  
(collectively, "Defendants") for their Answer against Plaintiffs, by and through their attorneys,  
answer as follows:

**THE PARTIES**

1. Taro Pharmaceuticals North America, Inc. is a corporation organized and existing under the laws of the Cayman Islands, having its principal place of business at 103 South Church Street, Grand Cayman, Cayman Islands.

**ANSWER:**

**1. Upon information and belief, Defendants admit the allegations set forth in paragraph 1.**

2. Taro Pharmaceuticals U.S.A., Inc. is a corporation organized and existing under the laws of the State of New York, having a place of business at 3 Skyline Drive, Hawthorne, New York.

**ANSWER:**

**2. Upon information and belief, Defendants admit the allegations set forth in paragraph 2.**

3. Upon information and belief, Defendant Synerx Pharma, LLC ("Synerx") is a corporation organized and existing under the laws of the State of Pennsylvania, having a place of business at 100 North State Street, Newton, Pennsylvania.

**ANSWER:**

**3. Synerx admits, and upon information and belief DPT admits, that Synerx is a corporation organized and existing under the laws of the State of Pennsylvania, having a place of business at 100 North State Street, Newtown, Pennsylvania. Defendants otherwise deny the allegations set forth in paragraph 3.**

4. Upon information and belief, Defendant Karalex Pharma, LLC ("Karalex") is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 470 Chestnut Ridge Road, Woodcliff, New Jersey.

**ANSWER:**

**4. Karalex Pharma, LLC ("Karalex") is no longer a party to this litigation. Defendants Synerx and DPT are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4 of the Complaint, and therefore deny them.**

5. Upon information and belief, Karalex is registered to do business in New Jersey and has appointed Frank Fazio as its registered agent in New Jersey for receipt of service of process.

**ANSWER:**

**5. Karalex is no longer a party to this litigation. Defendants Synerx and DPT are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 5 of the Complaint, and therefore deny them.**

6. Upon information and belief, Defendant DPT Laboratories, Ltd. ("DPT") is a corporation organized and existing under the laws of the State of Texas, having places of business at 1700 Oak Street, Lakewood, New Jersey, and 307 East Josephine Street, San Antonio, Texas.

**ANSWER:**

**6. DPT denies, and upon information and belief Synerx denies, the allegations set forth in paragraph 6. DPT Laboratories, Ltd. is a Texas Limited Partnership organized and existing under the laws of the State of Texas, having a place of business at 307 East Josephine Street, San Antonio, Texas. DPT Lakewood, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 1700 Oak Street, Lakewood, New Jersey.**

#### **JURISDICTION AND VENUE**

7. This action arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* This court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a).

**ANSWER:**

**7. Defendants admit that the Complaint purports to assert claims for patent infringement of United States Patent Number 7,560,445 ("the '445 patent") arising under the United States patent laws, and that this Court has subject matter jurisdiction over the**

**cause of action stated in the Complaint. Defendants otherwise deny the allegations set forth in paragraph 7.**

8. Venue is proper in this judicial district pursuant to Title 28 of the United States Code, §§ 1391 and 1400(b).

**ANSWER:**

**8. Defendants do not contest venue in this judicial district for purposes of this action only. Defendants otherwise deny the allegations set forth in paragraph 8.**

9. This Court has personal jurisdiction over Synerx because it continuously and systematically transacts business in New Jersey, and committed acts within this judicial district that give rise to this action.

**ANSWER:**

**9. Synerx does not contest this Court's exercise of personal jurisdiction over it for purposes of this action only. Synerx otherwise denies the allegations set forth in paragraph 9. DPT lacks sufficient information to form a belief as to the truth of the allegations in paragraph 9 and therefore denies those allegations.**

10. This Court has personal jurisdiction over Karalex because it continuously and systematically transacts business in New Jersey, it resides in the State of New Jersey, and committed acts within this judicial district that give rise to this action.

**ANSWER:**

**10. Karalex is no longer a party to this litigation. Defendants Synerx and DPT are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 10 of the Complaint, and therefore deny them.**

11. This Court has personal jurisdiction over DPT because it continuously and systematically transacts business in New Jersey, operates a facility in the State of New Jersey, and committed acts within this judicial district which give rise to this action.



**ANSWER:**

**11. DPT does not contest this Court's exercise of personal jurisdiction over it for purposes of this action only. DPT otherwise denies the allegations set forth in paragraph 11. Synerx lacks information sufficient to form a belief as to the truth of the allegations in paragraph 11 and therefore denies those allegations.**

**CLAIM FOR PATENT INFRINGEMENT**

12. On July 14, 2009, United States Patent No. 7,560,445 ("the '445 patent") entitled "Process for Preparing Malathion for Pharmaceutical Use," was duly and legally issued by the U.S. Patent and Trademark Office to Taro Pharmaceuticals North America, Inc. Taro Pharmaceuticals North America, Inc. is the owner of all right, title, and interest in the '445 patent, including the right to sue for infringement. A copy of the '445 patent is attached hereto and incorporated herein as Exhibit A.

**ANSWER:**

**12. Defendants admit that a copy of U.S. Patent No. 7,560,445 ("the '445 patent") is attached to the Complaint as Exhibit A. Defendants further state that the assignee listed on the face of the '445 patent is Taro Pharmaceuticals North America, Inc., and that the issue date listed on the face of the '445 patent is July 14, 2009. Defendants deny the remaining allegations set forth in paragraph 12.**

13. Taro Pharmaceuticals North America, Inc. holds an approved New Drug Application for 0.5% malathion topical lotion, which is sold under the registered trademark OVIDE®.

**ANSWER:**

**13. Upon information and belief, Defendants admit the allegations set forth in paragraph 13.**

14. Taro Pharmaceuticals U.S.A., Inc., an affiliate of Taro Pharmaceuticals North America, Inc., distributes OVIDE® in the United States.

**ANSWER:**

**14. Defendants lack sufficient information as to the allegations set forth in paragraph 14, and therefore neither admit nor deny those allegations.**

15. OVIDE® (malathion) Lotion, 0.5%, was originally approved on August 2, 1982, by the U.S. Food and Drug Administration ("FDA") for treatment of patients infected with *Pediculus humanus capitis* (head lice and their ova) of the scalp hair.

**ANSWER:**

**15. Upon information and belief, Defendants admit the allegations set forth in paragraph 15.**

16. Upon information and belief, Synerx obtained approval on March 6, 2009, for its Abbreviated New Drug Application No. 078743, covering 0.5% Malathion Topical Lotion, as a generic version of Taro's OVIDE® (malathion) Lotion.

**ANSWER:**

**16. Defendants admit the allegations set forth in paragraph 16.**

17. Upon information and belief, Synerx's generic version of OVIDE® (malathion) Lotion infringes one or more claims of the '445 patent.

**ANSWER:**

**17. Defendants deny the allegations set forth in paragraph 17.**

18. Upon information and belief, Karalex is offering for sale, selling and/or distributing the Synerx generic version of Taro's OVIDE® (malathion) Lotion.

**ANSWER:**

**18. Defendants deny the allegations set forth in paragraph 18.**

19. Upon information and belief, DPT is manufacturing the Synerx generic version of Taro's OVIDE® (malathion) Lotion.

**ANSWER:**

**19. Defendants deny the allegations set forth in paragraph 19.**

20. Each of the Defendants has infringed and continues to infringe the '445 patent, either directly, by contributory infringement and/or by inducement of others to infringe. The infringing acts include, but are not limited to, the manufacture, use, sale, importation, and/or offer for sale of products covered by the '445 patent. Each of the Defendants is liable for infringement of the '445 patent pursuant to 35 U.S.C. § 271.

**ANSWER:**

**20. Defendants deny the allegations set forth in paragraph 20.**

21. Each of the Defendants' acts of infringement has caused damage to Taro, and Taro is entitled to recover from each Defendant the damages sustained by Taro as a result of each Defendants' individual wrongful acts in an amount subject to proof at trial. Each of the Defendants' infringement of Taro's exclusive rights under the '445 patent will continue to damage Taro's business, causing irreparable harm, for which there is no adequate remedy at law, unless it is enjoined by this Court.

**ANSWER:**

**21. Defendants deny the allegations set forth in paragraph 21.**

22. Upon information and belief, Defendants' infringement of the '445 patent is willful and deliberate, entitling Taro to increased damages under 35 U.S.C. § 284 and to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

**ANSWER:**

**22. Defendants deny the allegations set forth in paragraph 22.**

#### **AFFIRMATIVE DEFENSES**

Further responding to the Complaint and as additional defenses thereto, Defendants assert the following affirmative defenses, without admitting any allegations of the Complaint not

otherwise admitted and without assuming the burden when such burden would otherwise be on Plaintiffs.

**FIRST AFFIRMATIVE DEFENSE**  
**(Invalidity of the '445 Patent)**

23. One or more claims of the '445 patent are invalid for failing to meet one or more conditions for patentability set forth in 35 U.S.C. § 101 *et seq.* By way of example and not of limitation, one or more claims of the '445 patent are invalid under 35 U.S.C. § 103.

**SECOND AFFIRMATIVE DEFENSE**  
**(Invalidity of the '445 Patent)**

24. One or more claims of the '445 patent are invalid for failing to meet one or more conditions for patentability set forth in 35 U.S.C. § 101 *et seq.* By way of example and not of limitation, one or more claims of the '445 patent are invalid under 35 U.S.C. § 102.

**THIRD AFFIRMATIVE DEFENSE**  
**(Invalidity of the '445 Patent)**

25. One or more claims of the '445 patent are invalid for failing to meet one or more conditions for patentability set forth in 35 U.S.C. § 101 *et seq.* By way of example and not of limitation, one or more claims of the '445 patent are invalid under 35 U.S.C. § 112.

**FOURTH AFFIRMATIVE DEFENSE**  
**(Non-Infringement of the '445 Patent)**

26. The manufacture, use, offer for sale, or importation of Defendants' malathion products that are the subject of ANDA No. 078743 will not infringe any valid claim of the '445 patent.

**FIFTH AFFIRMATIVE DEFENSE**  
**(Non-Infringement of the '445 Patent)**

27. Synerx and DPT have not made, offered for sale, sold, distributed, imported or used Defendants' malathion products that are the subject of ANDA No. 078743 during the term of the '445 patent other than uses protected under 35 U.S.C. § 271(e)(1).

**SIXTH AFFIRMATIVE DEFENSE**  
**(Failure to State a Claim)**

28. To the extent the Complaint purports to allege that this case is exceptional within the meaning of 35 U.S.C. § 285 and seeks an award of attorneys fees, the Complaint fails to state a claim upon which relief can be granted.

**COUNTERCLAIM OF SYNERX FOR DECLARATION**  
**OF INVALIDITY OR NONINFRINGEMENT**

Further responding to the Complaint, Synerx makes the following counterclaims:

**THE PARTIES**

29. Counter-plaintiff Synerx Pharma LLC ("Synerx") is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a principal place of business at 100 North State Street, Newtown, Pennsylvania.

30. On information and belief based on the allegations of the Complaint, Taro Pharmaceuticals North America is a corporation organized and existing under the laws of the Cayman Islands, having its principal place of business at 103 South Church Street, Grand Cayman, Cayman Islands.

31. On information and belief based on the allegations of the Complaint, Taro Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the State of New York, having a place of business at 3 Skyline Drive, Hawthorne, New York. Taro

Pharmaceuticals North America, Inc. and Taro Pharmaceuticals USA Inc. are referenced herein collectively and individually as “Taro.”

### **THE CONTROVERSY**

32. On information and belief based on the allegations of the Complaint, Taro is the owner of U.S. Patent No. 7,560,445 (the “445 patent”). The ‘445 patent is directed to the purity of malathion.

33. On information and belief based on the allegation of the Complaint, Taro holds an approved New Drug Application (NDA) for 0.5% malathion topical lotion (hereinafter “the NDA product.”)

34. Synerx is the owner of Abbreviated New Drug Application No. 078743, which is directed to a generic version of the NDA product. Synerx received FDA approval on March 6, 2009 for this generic malathion product.

35. Immediately upon receiving notice of Synerx’s FDA approval, and even before the ‘445 patent issued, Taro threatened Synerx with suit. In a letter dated March 12, 2009, Taro’s counsel warned Synerx that “a sale of a generic malathion lotion would violate Taro’s rights.”

36. As of March 12, 2009, on information and belief, Taro had no test data or other information showing the impurity profile of the malathion in Synerx’s generic malathion product.

37. Despite Taro’s threat, Synerx went forward with commercialization of its generic malathion product, and sold it into the marketplace.

38. On July 14, 2009, the '445 patent issued. Two weeks later, Taro sued Synerx for infringement of the '445 patent.

39. Upon information and belief, Taro sued both the manufacturer of Synerx's generic malathion product and the wholesaler of Synerx's generic malathion product, without independent investigation concerning whether any allegedly infringing manufacture or sales had occurred during the term of the '445 patent. Despite representations from both the manufacturer and the wholesaler that no such sales had taken place, Taro continues to maintain its lawsuit.

40. On information and belief based at least on the suits brought against Synerx's co-defendants, Taro is using the '445 patent in an effort to interfere improperly with Synerx's continued commercialization of a generic malathion product.

41. On information and belief, Taro will continue to use the '445 patent to interfere with Synerx's commercialization of its generic malathion product until and unless the claims of that patent are declared invalid or not infringed by Synerx's malathion product.

42. Synerx plans to continue having its generic malathion product manufactured and marketed. Synerx is thus in a position of either pursuing behavior that Taro claims is illegal, or abandoning that which Synerx claims a right to do.

#### **JURISDICTION AND VENUE**

43. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that it arises under the patent laws of the United States.

44. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because this is, as described above, a case of actual controversy

within the Court's jurisdiction. Synerx is entitled to seek a declaratory judgment that the claims of the '445 patent are either invalid or not infringed.

45. Venue is proper in this District pursuant to 28 U.S.C. §1391.

**THE CLAIMS OF THE PATENT ARE INVALID OR NOT INFRINGED**

46. Upon information and belief, in 1982 the FDA granted final approval to New Drug Application No. 18-613 covering a 0.5% malathion product for treatment of head lice.

47. Taro is the holder of New Drug Application No. 18-613 covering a 0.5% malathion product.

48. More than one year prior to the priority date of the '445 patent, a malathion-containing product called "Ovide® (malathion) Lotion 0.5%" was sold in the United States (hereinafter "the prior art Ovide® lotion").

49. Every claim of the '445 patent includes a limitation specifying the level of an impurity called "methyl malathion" ("the methyl malathion limitation").

50. The '445 patent describes two different chemical compounds as "methyl malathion": one compound having phosphorous double bonded to sulfur (*see* col. 5, line 65-col. 6, line 2), and the other compound having the same phosphorous double bonded to oxygen (*see* col. 22, lines 43-46).

51. On information and belief, one or more batches of the prior art Ovide® lotion contained between 0.1% and 0.2% methyl malathion as defined in col. 5, line 65 - col. 6, line 2 of the '445 patent. These batches contain an amount of methyl malathion that falls outside of the methyl malathion limitation of all of the '445 patent's composition claims.



52. On information and belief, the prior art Ovide® lotion contained less than 0.02% methyl malathion as defined in col. 22, lines 43-46 of the '445 patent. These batches contain an amount of methyl malathion that would fall within the methyl malathion limitation of all of the '445 patent's composition claims.

53. Multiple articles published more than a year before the priority date of the '445 patent report the preparation of malathion of greater than 99.9% purity.

54. Malathion of greater than 99.9% purity contains less than 0.1% total impurities and less than 0.1% of any single impurity.

55. At the time of the alleged invention of the '445 patent, malathion was known to contain impurities that were more toxic to mammals than malathion itself.

56. At the time of the alleged invention of the '445 patent, it was known to a person of ordinary skill in the art that malathion was the pharmaceutically-useful component of the prior art Ovide® lotion.

57. At the time of the alleged invention of the '445 patent, it would have been obvious to a person of ordinary skill in the art how to prepare malathion with the levels of impurities claimed in the '445 patent.

58. At the time of the alleged invention of the '445 patent, it would have been obvious to incorporate malathion with the levels of impurities claimed in the '445 patent into the prior art Ovide® lotion.

59. On information and belief, there is no unexpected result, commercial success or other secondary consideration favoring a conclusion of nonobviousness.

60. For at least the foregoing reasons, multiple claims of the '445 patent are invalid under 35 U.S.C. §§ 102, 103 and/or 112.

61. Multiple claims of the '445 patent, if they were valid, would not be infringed by Synerx's generic malathion product.

62. No valid claim of the '445 patent would be infringed by Synerx's product.

**PRAYER FOR RELIEF**

Wherefore, Synerx respectfully asks that the Court enter judgment against Taro to include:

- (a) a declaration that the generic malathion product described in ANDA No. 078743 does not infringe any valid claim of the '445 patent;
- (b) a declaration that one or more claims of the '445 patent are invalid under 35 U.S.C. § 102;
- (c) a declaration that one or more claims of the '445 patent are invalid under 35 U.S.C. § 103;
- (d) a declaration that one or more claims of the '445 patent are invalid under 35 U.S.C. § 112;
- (e) a declaration that Taro is entitled to no damages, interest, costs or other relief for infringement of the '445 patent pursuant to 35 U.S.C. § 271;
- (f) a declaration that Taro is entitled to no damages, interest, costs or other relief from or against Synerx pursuant to 35 U.S.C. §§ 283-285, or any other provision of law;
- (g) an award of Defendants' attorney fees and costs under 35 U.S.C. § 285, and
- (h) a grant of such other and further relief as the Court deems just and proper.

December 10, 2010

Respectfully submitted,

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